



Billing Code: 4150-44

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Written Comments on the Human Papillomavirus Working Group's Draft Report and Draft Recommendations for Improving Vaccination Rates in Adolescents for Consideration by the National Vaccine Advisory Committee.

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, National Vaccine Program Office.

ACTION: Notice.

SUMMARY: The National Vaccine Advisory Committee (NVAC) was established in 1987 to comply with Title XXI of the Public Health Service Act (P.L. 99-660) (§2105) ([42 U.S. Code 300aa-5 \(PDF - 78 KB\)](#)). Its purpose is to advise and make recommendations to the Director of the National Vaccine Program on matters related to program responsibilities. The Assistant Secretary for Health (ASH) has been designated by the Secretary of Health and Human Services (HHS) as the Director of the National Vaccine Program. The National Vaccine Program Office (NVPO) is located within the Office of the Assistant Secretary for Health (OASH), Office of the Secretary, U.S. Department of Health and Human Services (HHS). NVPO provides leadership

and fosters collaboration among the various federal agencies involved in vaccine and immunization activities. The NVPO also supports the National Vaccine Advisory Committee (NVAC). The NVAC advises and makes recommendations to the ASH in her capacity as the Director of National Vaccine Program on matters related to vaccine program responsibilities.

In February 2013, the NVAC created a working group to review the current state of HPV immunization, to understand the root cause(s) for the observed low vaccine uptake, both in initiation and in series completion, and to identify existing best practices to increase the use of the HPV vaccine in young adolescents.

Through a series of teleconferences, electronic communications, and public discussions during the NVAC meetings, a working group identified a number of draft recommendations categorized into five priority areas of opportunity for improving vaccination coverage among adolescents. The draft report and draft recommendations from the working group will inform NVAC deliberations as the NVAC finalizes their recommendations for transmittal to the ASH.

On behalf of NVAC, NVPO is soliciting public comment on the draft report and draft recommendations from a variety of stakeholders, including the general public. Comments will be considered by the NVAC as it develops its final recommendations to the ASH. It is anticipated that the draft report and draft recommendations, as revised with consideration given to public comment and stakeholder input, will be presented to the NVAC for discussion and adoption in NVAC meeting in June 2015.

DATES: Comments for consideration by the NVAC should be received no later than 5:00 p.m. EDT on [INSERT DATE 30 DAYS FOLLOWING DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

- 1) The draft report and draft recommendations are available on the web at <http://www.hhs.gov/nvpo/nvac/subgroups/nvac-hpv-wg.html>.
- 2) Electronic responses are preferred and may be addressed to: HPVwg@hhs.gov.
- 3) Written responses should be addressed to:

National Vaccine Program Office,
U.S. Department of Health and Human Services,
200 Independence Avenue, SW, Room 715H,
Washington, D.C. 20201.
Attn: HHS HPV Immunizations

FOR FURTHER INFORMATION CONTACT:

National Vaccine Program Office, Office of the Assistant Secretary for Health, Department of Health and Human Services; telephone (202) 690-5566; fax (202) 690-4631; email: HPVwg@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

There are an average of 25,900 newly diagnosed cases per year of human papillomavirus (HPV)-associated cancer in the United States. An estimated 14 million people are newly infected with HPV each year and nearly half of these infections occur in people between the ages of 14-25 years. While most infections resolve over time, persistent infection with oncogenic HPV types is associated with a variety of cancers. Virtually all cervical cancers are due to HPV along with 90 percent of anal, 69 percent of vaginal, 60 percent of oropharyngeal, 51 percent of vulvar, and 40 percent of penile cancers. Further, 87 percent of anal, 76 percent of cervical, 60 percent of oropharyngeal, 55 percent of vaginal, 44 percent of vulva and 29 percent of penile cancers are caused by oncogenic HPV types 16 or 18. Of the 35,000 HPV cancers reported in 2009 in the U.S., 39 percent occurred in males.

Through their analysis and discussion, the NVAC identified five major areas of opportunity:

- 1) Endorsing the President's Cancer Panel (PCP) report, Accelerating HPV Vaccine Uptake: Urgency for Action to Prevent Cancer, and adopt the recommendations outlined therein.
- 2) Monitoring "the status of uptake and implementation of the recommendations" through an annual progress report from HPV vaccination stakeholders identified in the PCP report.
- 3) Working with relevant agencies and stakeholders to develop evidence-based, effective, coordinated communication strategies to increase the strength and consistency of clinician recommendations for HPV vaccination to adolescents (both males and females) in the recommended age groups and to improve acceptance among parents/guardians, adolescents and young adults.

- 4) Working with the relevant agencies and stakeholders to strengthen the immunization system in order to maximize access to and support of adolescent vaccinations, including HPV vaccines.
- 5) Encouraging the review or development of available data that could lead to a simplified HPV vaccination schedule. In addition to a review that could impact existing vaccines, manufacturers of HPV vaccines in development should also consider opportunities to support the simplest HPV immunization schedule while maintaining vaccine effectiveness, safety, and long-term protection.

II. Request for Comment

NVPO, on behalf of the NVAC HPV Working Group, requests input on the draft report and draft recommendations. In addition to general comments on the draft report and draft recommendations, NVPO is seeking input on efforts or barriers to HPV immunization not represented in the report where HHS efforts could advance adolescent immunization efforts. Please limit your comments to six (6) pages.

III. Potential Responders

HHS invites input from a broad range of stakeholders including individuals and organizations that have interests in HPV immunization efforts and the role of HHS in advancing those efforts.

Examples of potential responders include, but are not limited to, the following:

- general public;
- advocacy groups, non-profit organizations, and public interest organizations;

- academics, professional societies, and healthcare organizations;
- public health officials and immunization program managers;
- adolescent provider groups including all physician and non-physician providers that administer healthcare services to adolescents, including pharmacists; and
- representatives from the private sector.

When responding, please self-identify with any of the above or other categories (include all that apply) and your name. Anonymous submissions will not be considered. Written submissions should not exceed six (6) pages. Please do not send proprietary, commercial, financial, business, confidential, trade secret, or personal information.

Dated: March 20, 2015.

Bruce Gellin,

Deputy Assistant Secretary for Health,

Director, National Vaccine Program Office,

Executive Secretary, National Vaccine Advisory Committee.

[FR Doc. 2015-07777 Filed: 4/3/2015 08:45 am; Publication Date: 4/6/2015]